

## **REMARKS**

Claims 1-6, 8-17, 38-41 and 51-52 are pending, and claims 7, 18-37, 41-50 and 53 have been cancelled without prejudice. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments contained herein.

### **REJECTION UNDER 35 U.S.C. § 102**

Claims 1-6, 8-9, 11-17, 23-25, 27-30, 33-35, 38-40 and 49-51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Osadchy et al. (U.S. Pat. No. 6,266,551). This rejection is respectfully traversed.

#### **Independent Claim 1**

The Applicant submits that Osadchy does not anticipate an interface that provides actuation instructions to the navigation device that take into account the physical and geometric properties of the elongate medical device including the number of magnetically responsive elements and spacing therebetween, where the navigation device is configured to determine, as a function of the physical and geometric properties, actuation control variables for an applied actuation consisting essentially of an external magnetic field.

Osadchy discloses a position signal generating device 28, where “magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals” and a computer uses “the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26”. (Osadchy, col. 10 line 55; col. 15, lines 6-7, 65-67). However, Osadchy only teaches “a handle 30 for operation of the catheter by a surgeon, wherein controls 32 on the handle enable the surgeon to steer the distal end of the catheter in a desired direction, or to position and/or orient it as desired”. (Osadchy, col. 10, ln 43-47).

Thus, contrary to claim 1, Osadchy does not teach or disclose a control system for controlling the position of the medical device, where a number of magnetically responsive elements and spacing therebetween are used in navigational control algorithms for guiding the device. As such, the Applicants submit that claim 38 is not anticipated by Osadchy.

The Office Action further states on page 5 (lines 4-11) that Osadchy's electronic identification device includes information on physical properties of the medical device including the position and orientation of a distal tip 26 relative to the coils, and that the position of the distal end must be necessarily taken into account for navigation control.

However, Osadchy's reference to information on a tip's location relative to a coil is not the same as physical and geometric properties of the elongate medical device including a number of magnetically responsive elements and spacing therebetween. Osadchy's distance is merely used as an offset to calibrate the actual position of the tip. This is not the same as properties of the device such as the number of magnetically responsive elements and spacing therebetween that will affect the forces required to deflect the device tip for navigation. Such properties are used in navigational control algorithms for guiding the device (see ¶¶ 30 and 31 of the application, "A navigational control algorithm determines a set of actuation control variables  $\{u\}$  that drive the device towards a user-specified target, where a functional relationship  $f$  of the control variable is based on the physics model of the flexible device."). As Osadchy does not disclose the feature of physical and geometric properties of the device including the number of magnetically responsive elements and spacing therebetween, the Applicants submit that claim 1 is not anticipated by Osadchy, and is allowable for at least these reasons.

### Claims 2-6 and 8-17

With regard to claims 2-6 and 8-17, these claims ultimately depend from claim 1, which the Applicants believe to be allowable in view of the above remarks. As such, the Applicants submit that claims 2-6 and 8-17 are also allowable for at least these reasons.

### Independent Claim 38

At the outset, the Applicants submit that the rejection of claim 38 has been rendered moot by the present amendments, which clarify that the memory includes information pertaining to physical and geometric properties "including one or more cross-sectional areas of the device and an elastic property" of the elongate medical device. The Applicant submits that Osadchy does not anticipate a control system for controlling the position of the distal end of the medical device, where one or more cross-sectional areas of the device and the elastic property of the device are used in navigational control algorithms for guiding the device.

Osadchy discloses a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (Osadchy, col. 10 line 55; col. 15, lines 6-7, 65-67). However, Osadchy only teaches "a handle 30 for operation of the catheter by a surgeon, wherein controls 32 on the handle enable the surgeon to steer the distal end of the catheter in a desired direction, or to position and/or orient it as desired". (Osadchy, col. 10, ln 43-47). Thus, contrary to claim 38, Osadchy does not teach or disclose a control system for controlling the position of the medical device, where a cross-sectional or elastic property of the device are used in navigational control algorithms for guiding the device. As such, the Applicants submit that claim 38 is not anticipated by Osadchy.

The Office Action further states on page 5 (lines 4-11) that Osadchy's electronic identification device includes information on physical properties of the medical device including the position and orientation of a distal tip 26 relative to the coils, and that the position of the distal end must be necessarily taken into account for navigation control.

However, Osadchy's reference to information on a tip's location relative to a coil is not the same as physical and geometric properties of the elongate medical device including one or more cross-sectional areas of the device and the elastic property of the device. Osadchy's distance is merely used as an offset to calibrate the actual position of the tip. This is not the same as properties of the device such as the cross-section or elastic property of the device that will affect the forces required to deflect the device tip for navigation. Such properties are used in navigational control algorithms for guiding the device (see ¶ 30 and 31 of the application, "A navigational control algorithm determines a set of actuation control variables  $\{u\}$  that drive the device towards a user-specified target, where a functional relationship  $f$  of the control variable is based on the physics model of the flexible device."). As Osadchy does not disclose the feature of physical and geometric properties of the device including one or more cross-sectional areas or an elastic property of the device, the Applicants submit that claim 38 is not anticipated by Osadchy, and is allowable for at least these reasons.

#### Claims 2-6 and 8-17

With regard to claims 2-6 and 8-17, these claims ultimately depend from claim 1, which the Applicants believe to be allowable in view of the above remarks. As such, the Applicants submit that claims 2-6 and 8-17 are also allowable for at least these reasons.

### REJECTION UNDER 35 U.S.C. § 103

Claim 52 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Osadchy et al. (U.S. Pat. No. 6,266,551) in view of Hall et al. (U.S. Pat. No. 6,428,551).

This rejection is respectfully traversed.

#### Claim 52

At the outset, the Applicant submits that the combination of Osadchy and Hall do not render obvious the claimed features of:

- a memory device provided with a medical device that includes information on the physical and geometric properties of the medical device relevant to navigational control of the device
- a control system for controlling the position and/or orientation of the distal end of the elongate medical device, wherein the control system is a magnetic navigation system for controlling an elongate medical device that further includes at least one magnet, and said information includes physical properties of the elongate medical device including at least a magnet dimension or a magnet type
- actuation instructions to the control system dependent in part upon the medical device's physical and geometric property information including the magnet dimension or magnet type

While Osadchy teaches a memory device provided with a medical device that includes a distance relating to a tip's location relative to a coil, Osadchy does not teach a control system for controlling the position of the distal end of the medical device. Rather, Osadchy teaches a handle 30 for operation of the catheter by a surgeon.

Hall teaches a system for applying a magnetic field that causes the deflection of a medical device having a magnet. However, the combined teachings of Osadchy and Hall do not render obvious information in a memory on a medical device that includes at least a magnet dimension or a magnet type, where actuation instructions to the control system are dependent in part on the magnet dimension or the magnet type of the

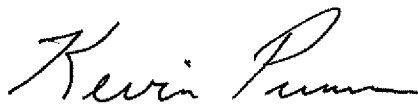
medical device. Thus, various types of medical devices having different magnet dimensions or magnet types may have different actuation instructions to the control system dependent in part on the information associated with the type of medical device. As the references do not suggest this feature, the Applicants submit that claim 52 is non-obvious and distinguished over the references, and is allowable for at least these reasons.

#### CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314)-726-7500.

Respectfully submitted,

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By:   
Kevin Pumm, Reg. No 49,046

Harness, Dickey & Pierce, P.L.C.  
7700 Bonhomme, Suite 400  
St. Louis, Missouri 63105  
(314) 726-7500